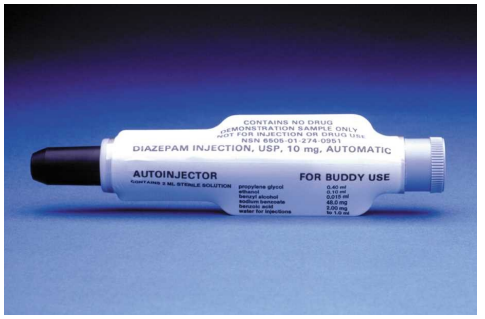


DoD/FDA Shelf Life Extension Program (SLEP)

Defense Medical Standization Board (DMSB
Joint Readiness Clinical Advisory Board (JRCA

DMSB/JRCAB History and Mission

- Began in 1945 as the Army-Navy Specification Cataloging Committee
- In 1984 became the Defense Medical Standardization Board (DMSB)
- 1986 DMSB tasked as Quad Service interface to the FDA for the DoD/FDA SLEP
- In 1998 name provisionally changed to Joint Readiness Clinical Advisory Board (JRCAB)
- In 2002, FDA allowed the National Strategic Pharmaceutical Stockpile (NSPS) to be added to the DoD/FDA SLEP under the JRCAB interface to the FDA
- 2003- updating and moving the automation for DoD/FDA SLEP to an Oracle/Web system

MISSION

- **Maintain the DoD/FDA Shelf Life Extension Program**
- **Provide standardized clinical patient treatment protocols for patient conditions (PCs)**
- **Standardized medical materiel/resources for delivery of healthcare in deployable medical systems (DEPMEDS) and in the Military Health Services System**

DoD/FDA Shelf Life Extension Program

- **All Pharmaceutics are controlled by the FDA**
- **New products (including new manufacturers or change in packaging/manufacturing) are given a maximum of a 2 year Shelf Life**
- **The DoD/FDA SLEP is limited to:**

  Army Air Force DSCP (does not currently participate)

  Navy Marines

  Strategic National Stockpile (SNS)
- **NO other Federal or Civilian agency may legally use the program**

DoD/FDA Shelf Life Extension Program

- **Substantial investments in replacement costs for war reserve potency dated medical material**
  - **Replacement cost in 1986 - $2.5 million subject of GAO Audit**

- **July 1985 - AF/SG office and FDA met**
  - **Established pilot project for concept testing**
  - **FDA established test protocols for 56 listed items**
  - **Samples of 56 items were sent to the FDA**

DoD/FDA Shelf Life Extension Program

- **January 1986 - interagency agreement was signed forming the program**

- **DMSB tasked as Quad-Service focal point**

- **In FY 1991 FDA increased dedicated program resources (facilities & personnel) due to expansion of new and retest projects**

DoD/FDA Shelf Life Extension Program

MSB/JRCAB serves a Liaison between Services /SNS & FDA

Services submit Samples for testing

FDA tests Military/contingency significant medications

FDA grants extension or denies extension of shelf-life, by Lot and NSN

Cost Avoidance to DoD Of $2.3M for $600K of testing in FY03

DoD/FDA Shelf Life Extension Program

- **Current testing focuses on military significant items**
  - **Drugs that are manufactured specifically for military use - e.g. auto-injectors, CANA, atropine, 2-Pam chloride….**
  - **Drugs that are purchased in very large quantities for specific contingency needs – e.g. Ciprofloxacin**
  - **Items that can not be returne Returns Programs**

- **Other drug products are co case-by-case**

DoD/FDA Shelf Life Extension Program

- **Test selection criteria:**
  - **Item cannot be a biological**
  - **FDA must have a test protocol for the item**
  - **Manufacturer's data for the item does not indicate previous instability**
  - **Cost beneficial for testing**
  - **Materiel must be stored under the manufacturer's recommended temperature**

- **FDA requests samples, various storage locations and lots, through DMSB/JRCAB to the Service field agency**

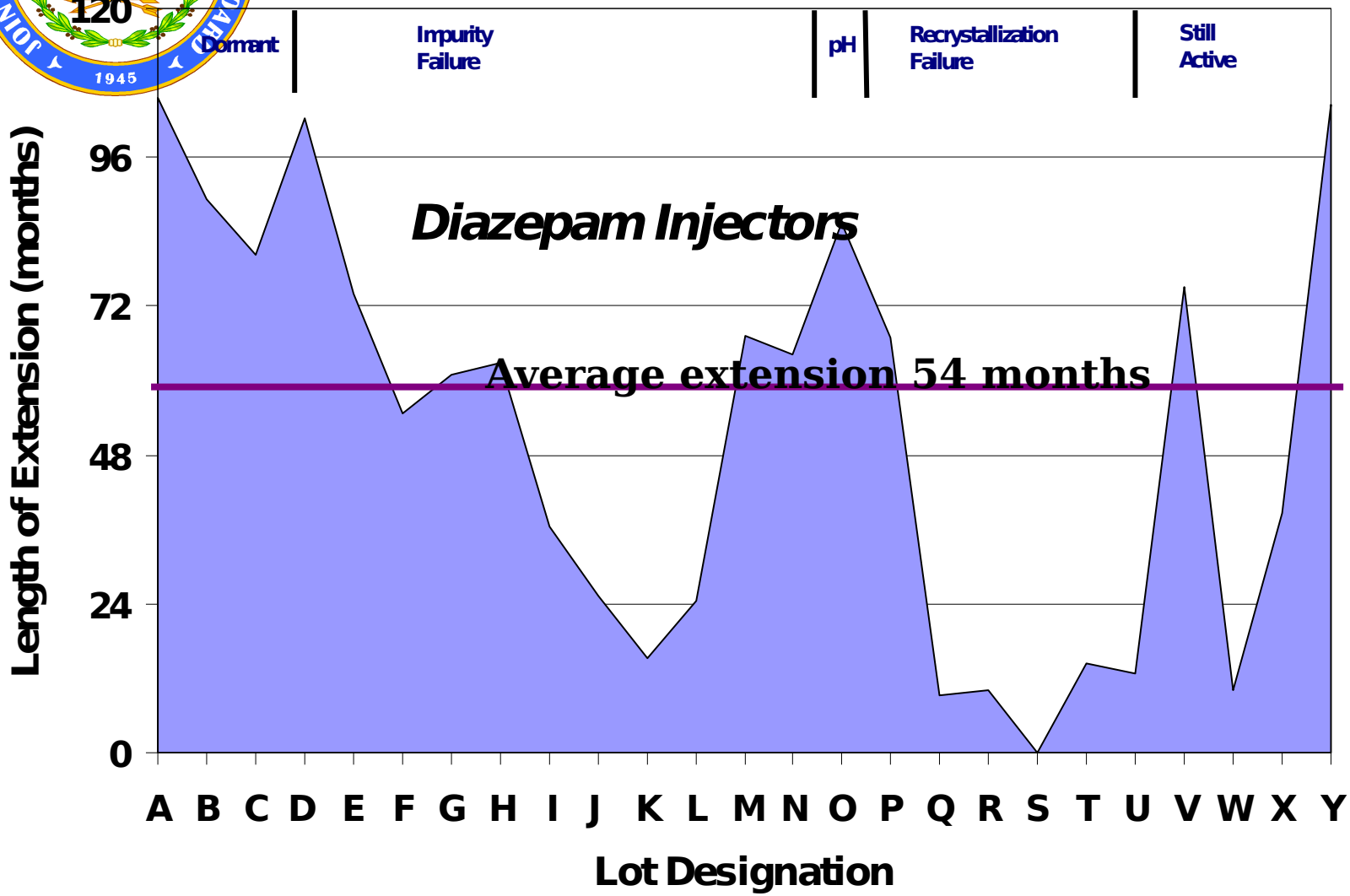
DoD/FDA Shelf Life Extension Program

- Field activities send samples to the FDA
- Products are tested and results are reported to the DMSB/JRCAB
- DMSB/JRCAB updates SLEP database, computes financial benefit and cost, orders labels (Dec 04) and distributes the information to the appropriate Service field agency
- Tested products are re-tested annually

FDA Testing

- **Test protocols from manufacturer's original product test data**
- **Accelerated testing (stress testing)**
  - **Designed to increase rate of chemical or physical degradation using exaggerated storage conditions**
- **Potency of stressed samples compared to standard for each item**
  - **Results in estimated extendible life of the product**

Extension Example



DoD/FDA Shelf Life Extension Program

- **FDA testing time-frame**
  - **8 months from the time the DMSB/JRCAB presents a project candidate list until project's extension information received by DMSB/JRCAB**

- **FDA testing is comprehensive and scientifically sound**
  - **Date extensions are conservative estimates of useful life of the product as substantiated by stress testing**

- **FDA grants extensions for all DoD facilities having the tested material stored under same conditions**
  - **Material specified by manufacturer, expiration date, lot number and storage condition**

DoD/FDA Shelf Life Extension Program

What materiel may be extended?

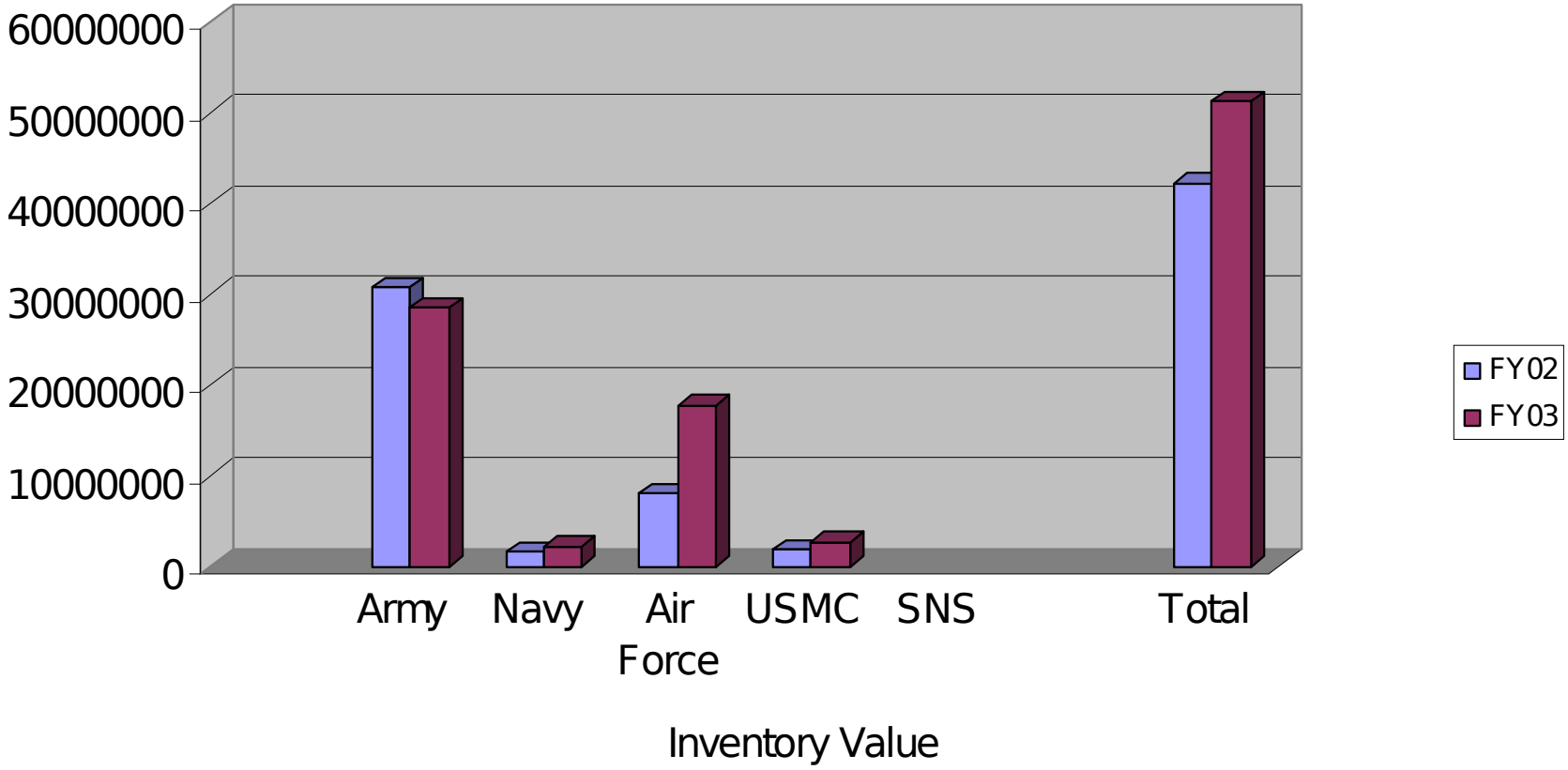
- Original Packaging or repacked by an approved FDA procedure.
- Must be stored at correct environmental standards IAW manufacturers literature.
- May not have been issued to an individual
- No leakage or failure of packaging, to include particles in solution, bulging or damage to packaging so product identification is missing or hard to read.

DoD/FDA Shelf Life Extension Program

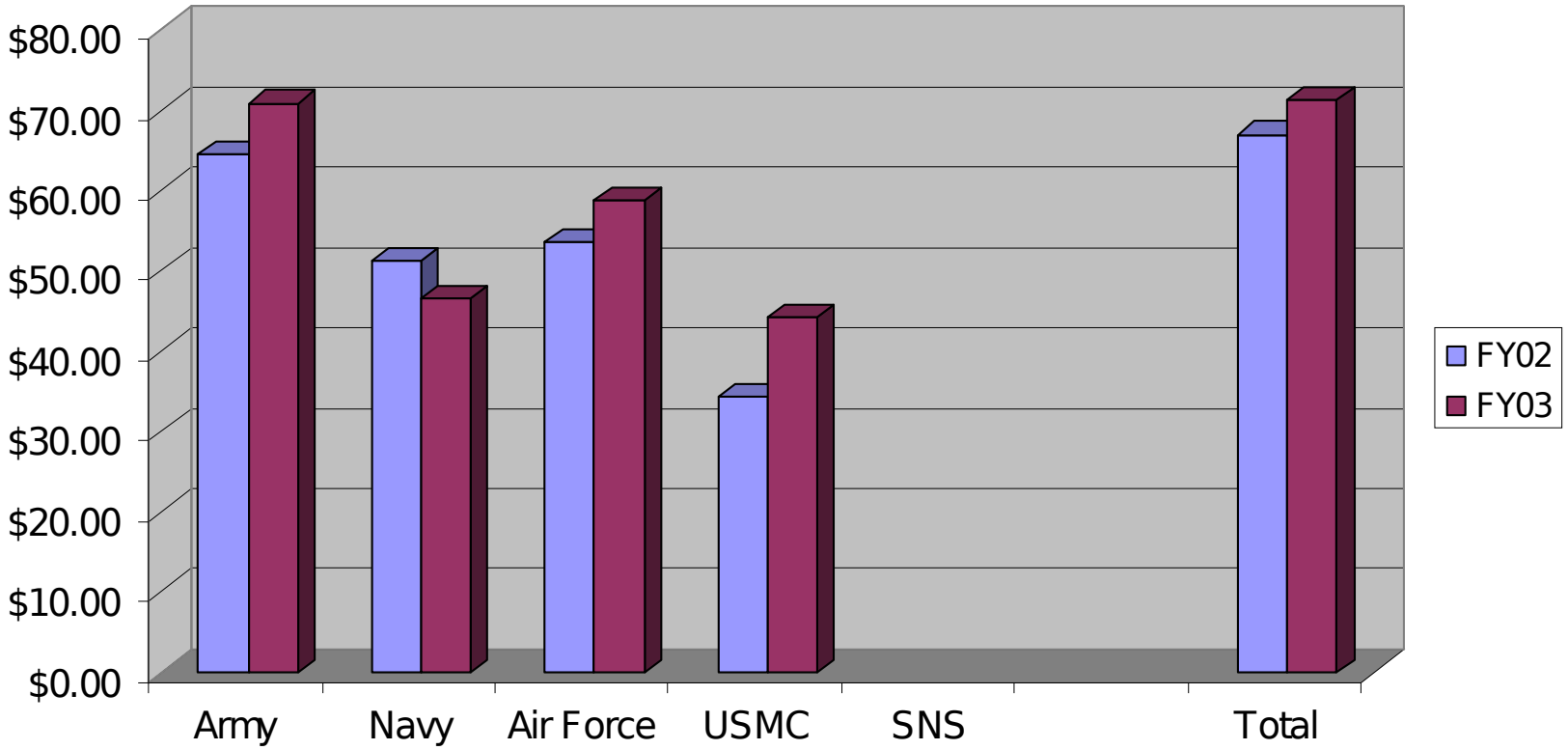
- **Average cost avoidance ratio is $71.00 for each dollar spent on testing in FY 03.**

- **Sample of cost for testing a lot is:**
  - **Atropine Injectors $1850.00**
  - **Ciprofloxacin $1800.00**
  - **2-Pam chloride $1000.00**
  - **CANA $2500.00**

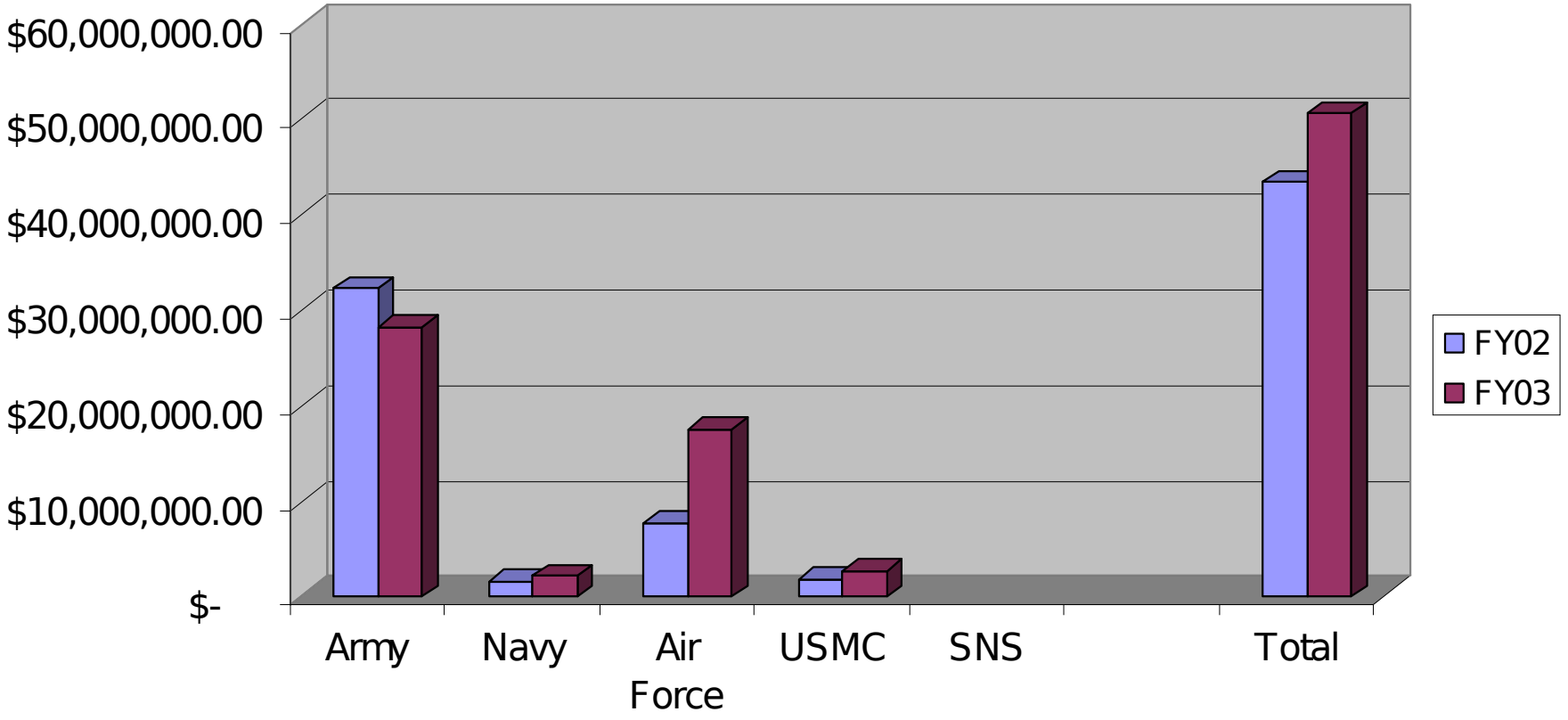
Total Inventory Values By Service



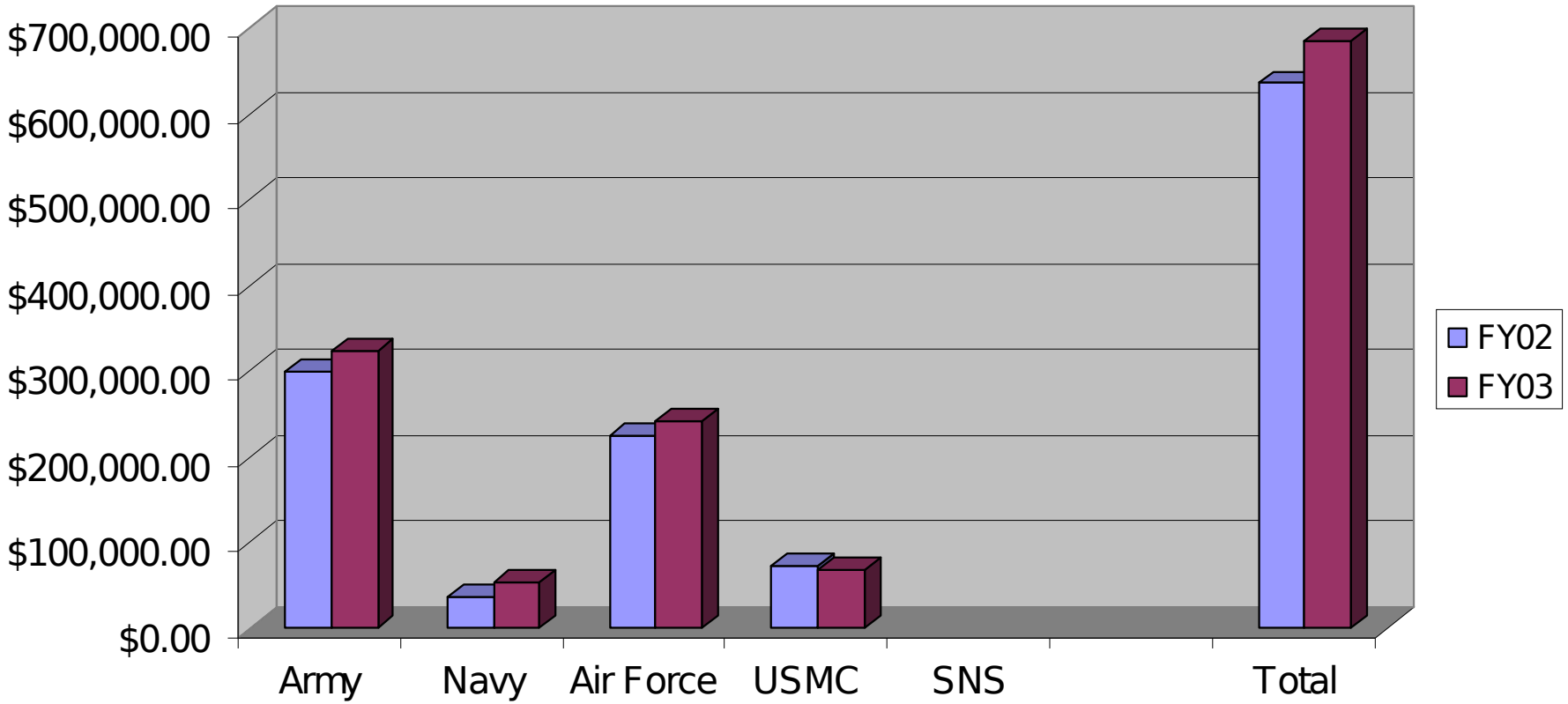
Return on Investment



Cost Avoidance



Cost of Testing



Changes in the DoD/FDA SLEP Progra

- SLEP currently operates in a client-server environment. Operators access the application, both the GUI and the database management system thru their desktop. The SLEP program is hosted in Microsoft Access 2000. A subcomponent of the SLEP system is hosted in Cold Fusion on the JRCAB current Web site. This component provides limited query capability. Only the POC from 3 of the 4 Services have access to the System. The Project Manager and Service POC must

- **The DMSB/JRCAB is currently moving to a DoD-approved/compliant enterprise level (Oracle), data base management system (DBMS). The GUI portion is migrating to a Web-based environment. This supports widened accessibility to the operators. The operators will now include all activities who have medical materiel on hand, that is in the DoD/FDA SLEP Program**

- **Moving the MMQC function from USAMMA to DMSB/JRCAB**

- **Change in the automation system for medical cataloging**

New Innovations :

- New Customers to the Program, the SNS, Post Office and possibly the VA.
- Addition of new products to program thought the SNS and New Military Unique items (i.e RSDL, QuickClot, HemoCon Bandage …)
- Addition of contract support
- Increase interface with other DoD and DoD SLEP systems, e.g. JMAR, DoD SLEP …

FDA Re-labeling Requirements

- **Food and Drug Administration Relabeling Mandate of 2002 is being modified. Waiting for final decision from the FDA.**

DoD/FDA Shelf Life Extension Program

- **POCs:**

  (301) 619-4074

  (301) 619-4126